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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/075,597

02/15/2002

Roy Sanders

2880/360

9386

23838

7590

06/29/2004

KENYON & KENYON

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WASHINGTON, DC 20005

EXAMINER

ROBERT, EDUARDO C

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/075,597	Applicant(s) SANDERS ET AL.	
	Examiner Eduardo C. Robert	Art Unit 3732	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 10-13 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/15/02, 7/22/03</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Election/Restrictions***

Applicant's election of Species I (Figure 1a) and Subspecies D (Figure 2c) in the reply filed on April 8, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without traverse** (MPEP § 818.03(a)).

It is acknowledged that applicant believes claims 1-5, 8, 9, 14, and 15 read on the elected Species and Subspecies. Also, it is acknowledged applicant's believe that claims 1, 9, 12 and 14 are generic. It is noted that comparison of the claims with Figures 1a and 2c and the specification shows, however, that the Species and Subspecies of Figures 1a and 2c do not have a recess that extends the entire length of the screw as required in claim 8. Furthermore, The Species and Subspecies of Figures 1a and 2c do not have a plurality of recesses in the proximal surface as required by claim 12. It is noted that in the election requirement mailed on March 8, 2004 the examiner indicated that claim 12 was a generic claim, however, after further consideration and for the reason stated above, it is clear that claim 12 is not a generic claim and it does not read on the elected Species/Subspecies.

In response to applicant's believe that claims 1, 9, 12, and 14 are generic claims, it is noted that claim 12 is not generic at least for the reason set forth above. Also, this appears to be reaffirmed by applicant since in the indication of claims readable on the elected Species/Subspecies applicant did not include claim 12. With to claim 1, it is noted that this claim is not generic because it does not read on the Subspecies of Figures 2a and 2b. Claim 1 requires

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“a recess ..... said recess comprising an odd number of rounded lobes ...” and clearly the embodiments of the Subspecies of Figures 2a and 2b do not have a single recess with odd number of rounded lobes. With regard to claim 9, it is noted that this claim is not generic because it does not read on the Subspecies of Figures 2a, 2b, and 2d. Claim 9 requires “a recess in said proximal surface ... said recess having three rounded lobes ... said lobes forming the cross-sectional shape of a cloverleaf” and clearly the embodiments of the Subspecies of Figure 2a, 2b, and 2d do not include these limitations. With regard claim 14, it is noted that this claim is not generic because it does not read on the Subspecies of Figures 2a, 2b, and 2d. Claim 14 requires the “lobes forming the cross-sectional shape of a cloverleaf” and clearly the embodiments of Figures 2a, 2b, and 2d do not include this limitation.

Claims 6-8, 10-13, and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species/Subspecies, there being no allowable generic or linking claim. The election, in the reply filed on April 8, 2004, was treated as an election **without** traverse because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

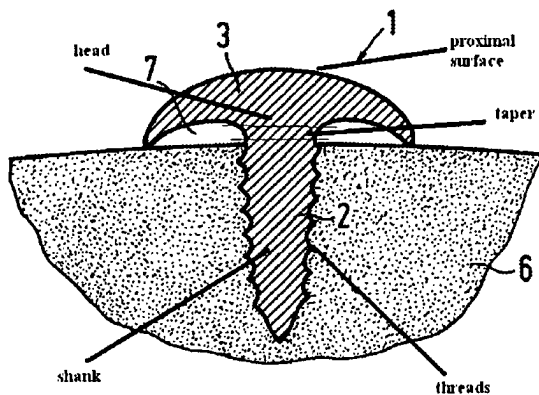
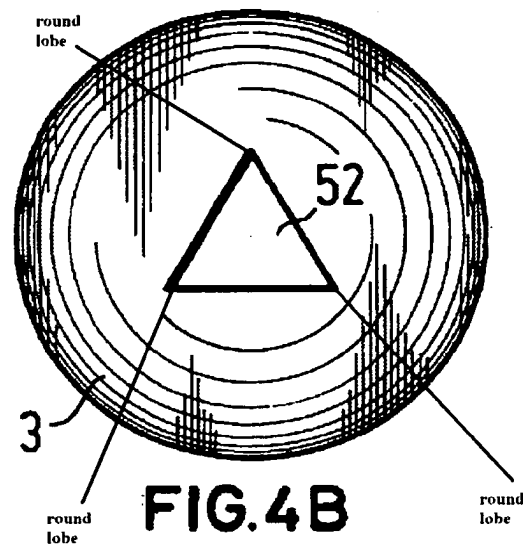
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Tormala et al. (U.S. Patent 6,015,410).

Tormala et al. disclose a surgical screw which is bioabsorbable in vivo and comprises an elongated shank with threads, a head perpendicular to a longitudinal axis of the shank, and the shank protruding from the head (see Figure 3 below). The head comprises a recess 52 in the proximal surface and the recess has a cross-section with a rotational symmetry around the longitudinal axis of the shank and wherein the recess has an odd number of rounded lobes, i.e. 3, extending away from the center of the head. It is noted that Figure 4b (see Figure 4b below) shows corners of the triangle with some degree of roundishness and this roundishness could be formed by a circle or oval located upon the triangle corners.

**FIG. 3****FIG. 4B**

The screw comprises self-reinforced material (see col. 7, lines 20-23). The head has a distal surface that tapers toward the shank (see Figure 3 above). With regard to claim 3, it is

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noted that the screw of Tormala et al. is made by machining (see col. 7, lines 34-35) and this includes clearly the formation of the recess.

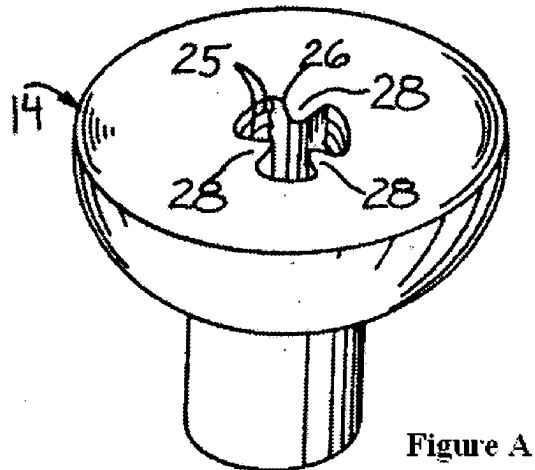
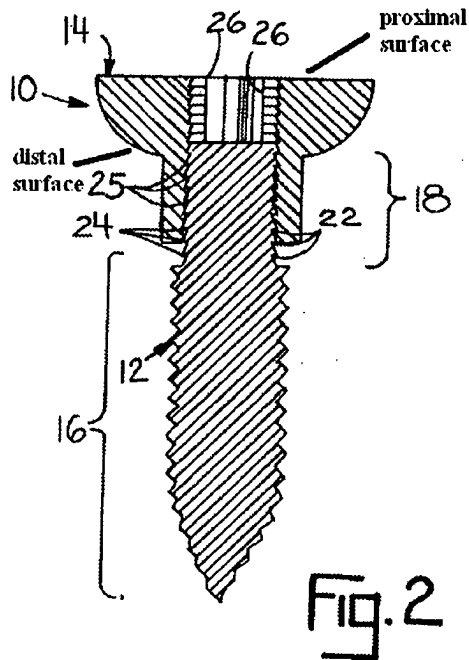
***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 9, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodorek (U.S. Patent 5,167,664) in view of Fallin (U.S. Patent 6,666,868).

Hodorek discloses a bone screw comprising an elongated shank 12 with threads, a head 14 having a proximal surface perpendicular to a longitudinal axis of the shank, and the shank protrudes from the head (see Figure 2 below). The head comprises a recess, e.g. 26, having a cross-section with a rotational symmetry around the longitudinal axis and wherein the recess includes an odd number of rounded lobes extending away from the center of the head (see Figure A below). It is noted that the lobes are formed from ovals located on the recess, thus forming a cloverleaf shape (see Figure A below). The head has a distal surface which tapers toward the shank (see Figure 2 below). Hodorek further discloses an inserter which is used with the recess of the head 14 (see col. 2, lines 34-37). Hodorek discloses the claimed invention except for screw being made from a bioabsorbable material.



Fallin teaches to construct bone screws of bioabsorbable material so that problems such as the screw being palpable under the skin or interference with certain types of diagnostic imaging are solved (see col. 1, lines 37-47). Hodorek also discloses that making bone screws of other material is well known in the art and within the skills of one skill in the art (see col. 5, lines 54, through col. 6, line 3). It would have been obvious to one skill in the art at the time the invention was made to construct the bone screw of Hodorek made from a bioabsorbable material in view of Fallin, in order to prevent problems such as the screw being palpable under the skin or interference with certain types of diagnostic imaging. Moreover, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. With regard to claim 3, it is noted that the device of the combination of Hodorek as modified by Fallin appears

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to be substantially identical to the device claimed, although produce by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983). With regard to claim 4, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone screw of the combination of Hodorek as modified by Fallin from self-reinforced biodegradable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hodorek (U.S. Patent 5,167,664) in view of Fallin (U.S. Patent 6,666,868) as applied to claim 14 above, and further in view of Hemer (U.S. Patent 5,019,080).

The combination of Hodorek and Fallin discloses the claimed invention except for the distal end of the inserter being progressively smaller towards the distal tip of the distal end. Hemer teaches to construct a distal end of an inserter 20 being progressively smaller toward a distal tip of the distal end in order to prevent possible wobbling of the screw when driven by the inserter (see Figure 1 and col. 4, lines 25-33, col. 5, lines 1-6, col. 3, lines 1-3, and 31-35). It would have been obvious to one skill in the art at the time the invention was made to construct the screw of the combination of Hodorek as modified by Fallin with the inserted distal end being progressively smaller towards the distal tip of the distal end in view of Hemer, in order to prevent wobbling of the screw when it is driven by the inserter.



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*Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Eduardo C. Robert  
Primary Examiner  
Art Unit 3732

E.C.R.